

LR. NO. 002230

## INVENTION RECORD

**NOTE:** Unless all questions are answered fully and the invention record signed, witnessed and dated, it will be returned to you for completion. Attach any additional pages, if necessary.

1. INVENTOR (Full name) ADDRESS (In full)  
John R. Peery \_\_\_\_\_ P.O. Box 10362 / Stanford CA 94309  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. TITLE OF INVENTION (See attached sheets for full description)  
Implant retention trocar \_\_\_\_\_  
\_\_\_\_\_

3. DATE CONCEIVED (date invention first thought of) \_\_\_\_\_

4. DATE INVENTION WAS FIRST DISCLOSED AND TO WHOM  
\_\_\_\_\_  
\_\_\_\_\_

5. DATE OF FIRST WRITTEN DESCRIPTION OF INVENTION

This is it \_\_\_\_\_

LOCATION OF WRITTEN RECORD? This is it \_\_\_\_\_

6. HAS INVENTION BEEN TESTED ON AN EXPERIMENTAL BASIS?

Yes. \_\_\_\_\_

WHEN? \_\_\_\_\_ WHERE? Bldg D, ALZA \_\_\_\_\_

RESULTS? Trocar punctured foil, picked up implant from gasketted package tube and implant was retained successfully.

7. HAS INVENTION BEEN DISCLOSED TO PERSONS OUTSIDE ALZA?

Yes. \_\_\_\_\_

IF SO, PLEASE RECITE CIRCUMSTANCES. \_\_\_\_\_

8. DOES INVENTION RELATE TO CONTRACTS WITH CLIENTS?

Yes. \_\_\_\_\_

WITH WHOM? Monsanto and perhaps Upjohn in their veterinary implant programs with ALZA. The Implant Retention Trocar may be also used in the HITS (Human Implanted Therapeutic System) implantation.

WHAT DRUG OR PRODUCT? bST (Bovine Somatotropin) and other drugs used in the VITS and ITS delivery systems.

9. DOES INVENTION RELATE TO CONTRACTS WITH A PARTNERSHIP (TTS or OROS) OR WITH BES?

No. \_\_\_\_\_

WITH WHOM? N/A \_\_\_\_\_

WHAT DRUG OR PRODUCT? N/A \_\_\_\_\_

## BACKGROUND OF THE INVENTION

### PURPOSE OF INVENTION

*State generally the purpose of the invention*

The invention is intended to serve three basic needs common to all implanted devices:

- 1) Puncture the foil or other cover of a sterile, sealed tubular or other package.
- 2) Facilitate "pickup" of the implant and retain it in the trocar for implantation.
- 3) Pierce the skin and penetrate the desired tissue layers to deposit the implant in the desired site without "coring" (cutting a cylindrical piece of tissue) that subsequently and undesirably traumatizes the organism and may prevent successful expulsion of the implant into the delivery site.

### ADVANTAGES OVER THE PRIOR ART

*State how the invention is an improvement over the prior art devices, apparatus, methods, articles or compositions. Additionally, state any existing problems and how the invention attempts to solve them.*

Prior art balling guns have been used in veterinary implantation procedures that succeed in retaining the implant or bolus tablet by interference fit with or distortion of the bolus holding means. On the other hand, these means are not readily amenable to incorporation into a trocar.

Prior art trocars exist that can be used to contain, yet not securely hold an implant. They rely upon the skill and care of the health care practitioner to orient the trocar so as to employ gravity to retain the implant, or in the case of many implants (ALZA's bioerodible systems included), the implant is capable of distorting to interfere with the wall of the trocar so as to keep it in place against the force of gravity.

This invention subject retains the implant within the trocar without grinding special features in the aluminum or stainless steel tube that comprises it. Such secondary operations are expensive and would prevent the trocar from being single-use. The retention means is produced by very inexpensive punching or photoetching, and can be inserted in a automated fashion. Thus the implant retention trocar may be used once and recycled or discarded.

The invention subject also, through a novel profile and grinding/sharpening pattern, enables puncture of the skin or hide, yet does not tend to core under normal use conditions.

These two attributes are entirely compatible in the invention trocar, where, by contrast, in prior art they are not.

In prior art, one can have retention in a specialty holder or a trocar with expensive secondary operations in manufacture. Or, one can have a conventional trocar with no retention. The invention disclosed here solves that dilemma.

## NOVELTY

*State what features of the invention you consider to be new.*

- 1) The profile of the leading edge of the trocar, which changes angles from the tip where the angle is relatively steep towards the "back", away from the tip where the angle is shallow to avoid coring or tearing tissue during trocar insertion into tissue and though the foil or other cover stock on the package containing the trocar.
- 2) The differential grind of the tip of the trocar, where the sharp grind of the tip or leading edge of the trocar differs from that of the trailing edge of the trocar where it is fully radiused.
- 3) The hammer-shaped leaf spring and its geometry which may be inexpensively fabricated and inserted within a trocar having the novel grind, above in 1&2, or within a conventional trocar. In either case, its thin, flat, but large-surface area geometry makes it easy to affix with instant (e.g. cyanoacrylate) or epoxy or polyester or other sterilization- and drug-compatible adhesive.
- 4) The tapered-tip plunger of the trocar which enables expulsion of the implant from the retention trocar without expelling the spring, as well.
- 5) The combination of the features 1-4, above, resulting in an inexpensive metal or plastic trocar which, through its low cost and manufacture of technologically recyclable materials, may be employed in single-use fashion.

## DESCRIPTION OF PRIOR ART

*List publications, patents, products, invention records, etc. which you consider to be pertinent to your invention.*

Publications: Syntex Synovex implantation gun instruction manual.  
Merck/ALZA Ivermectin delivery system instructions.  
Schering/ALZA Selenium delivery system instructions.  
Becton Dickinson / Yale products catalog.

Patents: Patent numbers unknown, but pertaining to and perhaps cited on the above publications and products.

Products: Products, above, described in the above instruction manuals.

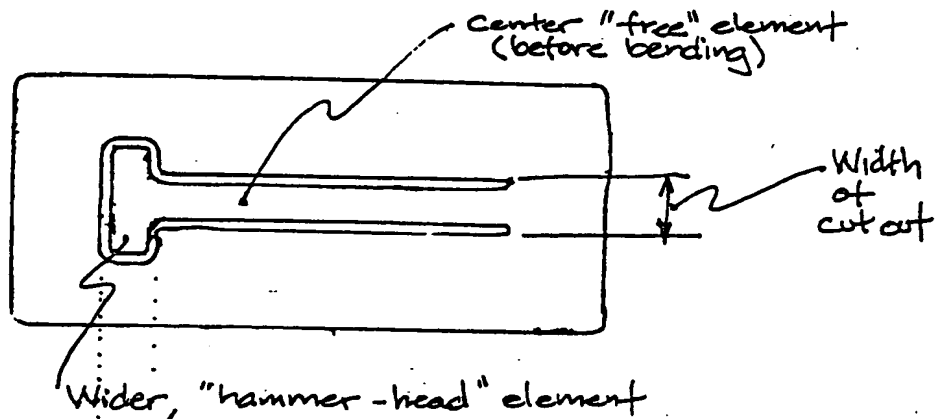
Invention records: Unknown.

## DETAILED DESCRIPTION OF THE INVENTION

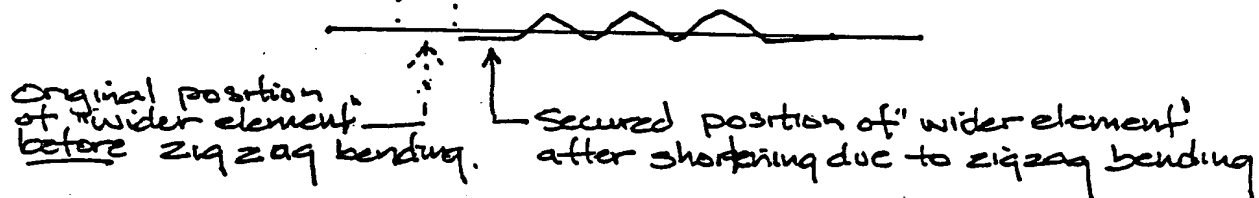
*Describe the invention fully. If the invention involves chemical reactions, please provide: ranges, ratio of reactants, temperatures, pressure, times or any other pertinent process variables. If the invention involves chemical compounds, please set forth: generic formulas, including definitions of any symbols. Describe the utility of the invention. Describe the preferred form of the invention along with any alternate configurations, modes of operation, etc.*

The invention comprises (though individual components may be able to stand alone in terms of patent coverage) a novel geometry and sharpening grind of an otherwise conventional trocar made of stainless steel, aluminum, engineering polymers, or other biocompatible materials that have high tensile strength, amenable to sharpening or retaining both sharp and radiused edges.

The leaf spring is punched, photoetched or similar of stainless steel or other metal or polymeric spring material in the following shape:



The spring has a long, center "free" element which is bent into a zigzag shape (when viewed on edge):

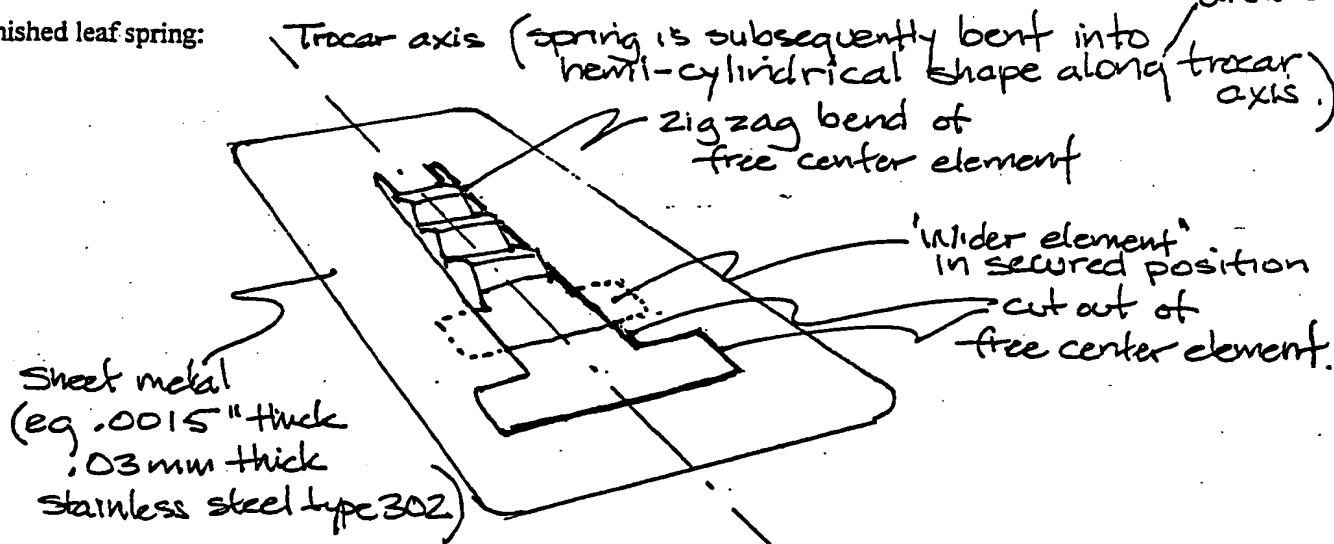


Bending the center free element has the effect of shortening the distance from the attachment point of the free section with the surrounding material to its wider, hammer-head (or similar wider feature—when viewed perpendicular to the flat material). Once shortened, the wider feature acts as a locking tab to secure the free end of the center leaf spring element.

The spring is rolled into a cylindrical shape and inserted within the tip of the trocar of choice. Cyanoacrylate, epoxy, polyester, acrylic, or other adhesive is used to secure the spring in place at the tip of the trocar. Thus, when an implant is inserted within the trocar, the zig-zag feature exerts force upon that implant to retain it until it is expelled by axial sliding of the plunger rod by the user.

The leaf spring may be alternately molded of a polymer into the same, basic shape.

Finished leaf spring:



The retention trocar also comprises a novel leaf spring that may be inexpensively produced of sheet metal or similar property material, bent into the desired configuration, inserted within a simple tubular trocar and adhesively affixed therein. A "hammer-shaped" geometry, wherein the free end of the center cutout of the zig-zag element is wider than the rest of the element, thus providing a tab that will slide under the cut out of the central element from the surrounding material to secure the central element from side-ways movement, yet allow it to move along the trocar axis as the zig-zag element is compressed to accommodate the implant. (See attached drawings and photographs.)

The invention also comprises a plunger shaped with a tapered tip to pass over the spring during implant expulsion from the trocar once the trocar is inserted through the hide or skin and positioned with its tip in or near to the desired implantation site. The plunger has a smaller tip, smaller than the resulting diameter of the open space within the trocar not occupied by the spring and then flares outward to a plunger having the same approximate diameter as the cylindrically-shaped implant.

**ATTACH COPIES OF RELEVANT NOTEBOOK PAGES, INCLUDING FIRST WRITTEN DESCRIPTION OF INVENTION**

**NOTE:** For this document to be properly witnessed, the witness must be a person who has read and understood the invention record, and therefore must be someone who is technically cognizant. Additionally, each signature must be witnessed and the witness can not be a co-inventor.

**SIGNATURES:**

INVENTOR J. R. Peery DATE             
SIGNED AT (City and State) Palo Alto, CA  
WITNESSED, READ AND UNDERSTOOD BY: William Roth  
DATE           

*[Handwritten mark]*